Abstract 347

TITLE: Results of a Laboratory Survey of HIV-1 Viral RNA Testing Practices and Report Content

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BACKGROUND/OBJECTIVES: The laboratory's role in HIV RNA testing (viral load testing) assumes new importance with the use of combined antiretroviral therapy for the HIV-1-infected patient. Determination of laboratory testing and reporting practices are important when designing QC/QA programs and promulgating guidelines for laboratories performing this testing. Knowledge of practice variables in testing may be an important consideration in selection of a testing laboratory.

METHODS: A telephone survey of laboratories believed most likely to perform viral load testing and/or p24 antigen testing was conducted. Laboratories were randomly selected from three source groups: medical schools, nationally advertised commercial laboratories and laboratories participating in the CDC Model Performance Evaluation Program. A laboratorian knowledgeable about HIV testing was interviewed. Respondents were also asked to fax or mail a copy of a negative and a positive HIV RNA report without patient identifiers.

RESULTS: A total 212 of 279 (76%) telephone surveys were completed. Of these 112 (52.8%) respondents performed HIV RNA testing. Of those performing viral load testing, 81.3% used the Roche Amplicor HIV-1 Monitor. Patient test volume for users of this kit ranged from 15 to 8000 tests per month. Chiron's Quantiplex branched DNA assay was the next most frequently used kit among the laboratories (26.8%, 30/112) with laboratories testing between 1 and 6000 patient specimens per month. Some laboratories (17, 15.2%) used more than one test kit. Among respondents, 52 (46.4%) used quality control material other than that provided by the kit manufacturer. Laboratory charges for an HIV RNA test ranged from $65 to $300. Respondents furnished HIV RNA reports representing 40 different laboratories. All laboratories reported results as copies/ml, with 10% also reporting the results designated as log copies/ml. On the report form, the test kit used was reported by 9 (22.5%) laboratories, 23 (57.5%) laboratories cited the kits' lower limit of detection, and only 13 (32.5%) reported the upper limit of detection. Of the 8 laboratories using methods not yet FDA licensed, 5 (62.5%) included a "for research only" disclaimer in the report. Four reports (10%) showed previous patient values for comparison.

CONCLUSIONS: The laboratory's report of test results is an integral part of laboratory testing and a component of the total testing process. Reports must be clear and concise, uncluttered by extraneous information, yet containing relevant information. The variability in the reports gathered during this survey suggests that report guidelines based on consensus may be necessary.

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